

# Technical Project Lead (TPL) Review of Exemption Requests: EX0001037, EX0001040, EX0001041, EX0001045, EX0001048 – EX0001050, and EX0001053 – EX0001060

Common Attributes of EX	K Requests	
Applicant	Al Fakher Distribution USA, Inc.	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
EX Requests Included in		
Tobacco Product	New	Original
Submission tracking number	EX0001037	GF1908361
Product name	Al Fakher Apple Flavour 1000 grams	Al Fakher Apple Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	1000 grams	1000 grams <sup>1</sup>
Characterizing flavor	Apple	Apple
Additional property:	Tobacco Cut Size:	Tobacco Cut Size:
	Tobacco Moisture: 🔐 %	Tobacco Moisture: 💦 %
	Addition/Deletion of tobacco additive	
Product modifications		e complex purchased flavor <sup>(b) (4)</sup> he complex purchased flavor <sup>(b) (4)</sup>

<sup>&</sup>lt;sup>1</sup> The package quanitiy was stated as 1 Kg, which was converted to 1000 grams.

Tobacco Product	New	Original	
Submission tracking	EX0001040	GF1908359	
number			
Product name	Al Fakher Apple Flavour 50 grams	Al Fakher Apple Flavour 50 grams	
Eligibility status	Not applicable	Grandfathered	
Marketing order date	Not applicable	Not applicable	
Abbreviated report date	Not applicable	Not applicable	
Packagetype	Plastic Pouch	Plastic Pouch	
Package quantity	50 grams	50 grams	
Characterizing flavor	Apple	Apple	
Additional property:	Tobacco Cut Size:	Tobacco Cut Size:	
	Tobacco Moisture: 😽 %	Tobacco Moisture: 🔐 %	
	Addition/Deletion of tobacco additive	s:	
		complex purchased flavor <sup>(b) (4)</sup>	
Product modifications			
	Addition of (b) (4) in t	he complex_purchased flavor <sup>(b) (4)</sup>	
Tobacco Product	New	Original	
Submission tracking	EX0001041	GF1908360	
number			
Product name	Al Fakher Apple Flavour 250 grams	Al Fakher Apple Flavour 250 grams	
	Al Fakher Apple Flavour 250 grams Not applicable	Al Fakher Apple Flavour 250 grams Grandfathered	
Product name			
Product name Eligibility status Marketing order date Abbreviated report date	Not applicable	Grandfathered	
Product name Eligibility status Marketing order date	Not applicable Not applicable	Grandfathered Not applicable	
Product name Eligibility status Marketing order date Abbreviated report date	Not applicable Not applicable Not applicable	Grandfathered Not applicable Not applicable	
Product name Eligibility status Marketing order date Abbreviated report date Package type	Not applicable Not applicable Not applicable Plastic Pouch	Grandfathered Not applicable Not applicable Plastic Pouch	
Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity	Not applicable Not applicable Not applicable Plastic Pouch 250 grams	Grandfathered Not applicable Not applicable Plastic Pouch 250 grams	
Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor	Not applicable Not applicable Not applicable Plastic Pouch 250 grams Apple	Grandfathered Not applicable Not applicable Plastic Pouch 250 grams Apple	
Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor	Not applicable Not applicable Not applicable Plastic Pouch 250 grams Apple Tobacco Cut Size:	Grandfathered Not applicable Not applicable Plastic Pouch 250 grams Apple Tobacco Cut Size: (b) mm Tobacco Moisture: (b) %	
Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor	Not applicable Not applicable Not applicable Plastic Pouch 250 grams Apple Tobacco Cut Size: mm Tobacco Moisture: M Addition/Deletion of tobacco additive	Grandfathered Not applicable Not applicable Plastic Pouch 250 grams Apple Tobacco Cut Size: (b) mm Tobacco Moisture: (b) %	
Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor	Not applicable Not applicable Not applicable Plastic Pouch 250 grams Apple Tobacco Cut Size: mm Tobacco Moisture: M Addition/Deletion of tobacco additive	Grandfathered Not applicable Not applicable Plastic Pouch 250 grams Apple Tobacco Cut Size: 00 mm Tobacco Moisture: 00 % s:	
Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor Additional property:	Not applicable Not applicable Not applicable Plastic Pouch 250 grams Apple Tobacco Cut Size: Mm Tobacco Moisture: M% Addition/Deletion of tobacco additive • Deletion of ( <sup>(b)(4)</sup> ) in the	Grandfathered Not applicable Not applicable Plastic Pouch 250 grams Apple Tobacco Cut Size: 00 mm Tobacco Moisture: 00 % s:	

Tobacco Product	New	Original	
Submission tracking	EX0001045	GF1908321	
number			
Product name	Al Fakher Mango Flavour 250 grams	Al Fakher Mango Flavour 250 grams	
Eligibility status	Not applicable Grandfathered		
Marketing order date	Not applicable Not applicable		
Abbreviated report date	Not applicable Not applicable		
Package type	Plastic Pouch Plastic Pouch		
Package quantity	250 grams	250 grams	
Characterizing flavor	Mango	Mango	
Additional property:	Tobacco Cut Size: 👸 mm	Tobacco Cut Size	
	Tobacco Moisture: 🔐 %	Tobacco Moisture: 🔐 %	
	Addition/Deletion of tobacco additive	25:	
Product modifications	Deletion of <sup>(b) (4)</sup> in the co	omplex purchased flavor <sup>(b) (4)</sup>	
FIGURETINGUINCATIONS	Increasing/Decreasing the quantity of	Equisting tobacco additives:	
	<ul> <li>Increasing the quantity of</li> </ul>		
	flavor (0) (4)	in the complex purchased	
Tobacco Product	New	Original	
Submission tracking	EX0001048	GF1908306	
number			
Product name	Al Fakher Strawberry Flavour 1000 Al Fakher Strawberry Fla grams		
Eligibility status	Not applicable	Grandfathered	
Marketing order date	Not applicable	Not applicable	
Abbreviated report date	Not applicable	Not applicable	
Packagetype	Plastic Pouch	Plastic pouch	
Package quantity	1000 grams	1000 grams <sup>1</sup>	
Characterizing flavor	Strawberry	Strawberry	
Additional property:	Tobacco Cut Size:	Tobacco Cut Size:	
	Tobacco Moisture: 🔐 %	Tobacco Moisture: 🔐 %	
Product modifications		es: e complex purchased flavor <sup>(b) (4)</sup> n the complex purchased flavor <sup>(b) (4)</sup>	

Tobacco Product	New	Original
Submission tracking	EX0001049	GF1908308
number		
Product name	Al Fakher Strawberry Flavour 50 gramsAl Fakher Strawberry Flavour 50	
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic pouch
Package quantity	50 grams	50 grams
Characterizing flavor	Strawberry	Strawberry
Additional property:	Tobacco Cut Size:	Tobacco Cut Size: 🖁 mm
	Tobacco Moisture: 🖁 %	Tobacco Moisture: 💏 %
Product modifications		complex purchased flavor <sup>(b) (4)</sup> the complex purchased flavor <sup>(b) (4)</sup>
Tobacco Product	New	Original
Submission tracking	EX0001050	GF1908303
number		
Product name	Al Fakher Strawberry Flavour 250	Al Fakher Strawberry Flavour 250
	grams	grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Packagetype	Plastic Pouch	Plastic pouch
Package quantity	250 grams	250 grams
Characterizing flavor	Strawberry	Strawberry
Additional property:	Tobacco Cut Size: 11 mm	Tobacco Cut Size: 11 mm
	Tobacco Moisture: 10%	Tobacco Moisture: 10%
Product modifications		: complex purchased flavor <sup>(b) (4)</sup> the complex purchased flavor <sup>(b) (4)</sup>

Tobacco Product	New	Original
Submission tracking	EX0001053	GF1908324
number		
Product name	Al Fakher Melon Flavour 250 grams Al Fakher Melon Flavour 250 gr	
Eligibility status	Not applicable Grandfathered	
Marketing order date	Not applicable Not applicable	
Abbreviated report date	Not applicable	Not applicable
Packagetype	Plastic Pouch	Plastic pouch
Package quantity	250 grams	250 grams
Characterizing flavor	Melon	Melon
Additional property:	Tobacco Cut Size:	Tobacco Cut Size: 🖁 mm
	Tobacco Moisture: 🖁 %	Tobacco Moisture: 🔐 %
	Increasing/Decreasing the quantity of	existing tobacco additives:
	<ul> <li>Increasing the quantity of <sup>(0)(4)</sup></li> </ul>	in the complex purchased
Product modifications	flavor <sup>10) (4)</sup>	
	• Decreasing the quantity of <sup>(b) (4)</sup>	in the complex purchased
	flavor <sup>(b) (4)</sup>	
Tobacco Product	New	Original
Submission tracking	EX0001054	GF1908323
number		
Product name	Al Fakher Melon Flavour 1000 grams	Al Fakher Melon Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing order date		
warketing of der date	Not applicable	Not applicable
Abbreviated report date	Not applicable Not applicable	Not applicable Not applicable
Abbreviated report date	Not applicable	Not applicable
Abbreviated report date Package type	Not applicable Plastic Pouch	Not applicable Plastic pouch
Abbreviated report date Package type Package quantity	Not applicable Plastic Pouch 1000 grams	Not applicable Plastic pouch 1000 grams <sup>1</sup>
Abbreviated report date Package type Package quantity Characterizing flavor	Not applicable Plastic Pouch 1000 grams Melon	Not applicable Plastic pouch 1000 grams <sup>1</sup> Melon
Abbreviated report date Package type Package quantity Characterizing flavor	Not applicable Plastic Pouch 1000 grams Melon Tobacco Cut Size: mm	Not applicable Plastic pouch 1000 grams <sup>1</sup> Melon Tobacco Cut Size: Tobacco Moisture: Melon Melon
Abbreviated report date Package type Package quantity Characterizing flavor	Not applicable Plastic Pouch 1000 grams Melon Tobacco Cut Size: mm Tobacco Moisture: %	Not applicable Plastic pouch 1000 grams <sup>1</sup> Melon Tobacco Cut Size: Tobacco Moisture: Melon Melon
Abbreviated report date Package type Package quantity Characterizing flavor	Not applicable Plastic Pouch 1000 grams Melon Tobacco Cut Size: mm Tobacco Moisture: % Increasing/Decreasing the quantity of	Not applicable Plastic pouch 1000 grams <sup>1</sup> Melon Tobacco Cut Size: mm Tobacco Moisture: Melon Tobacco doisture: Melon Tobacco doisture: Melon
Abbreviated report date Package type Package quantity Characterizing flavor Additional property:	Not applicable Plastic Pouch 1000 grams Melon Tobacco Cut Size: mm Tobacco Moisture: % Increasing/Decreasing the quantity of Increasing the quantity of	Not applicable Plastic pouch 1000 grams <sup>1</sup> Melon Tobacco Cut Size: mm Tobacco Moisture: Melon Tobacco doisture: Melon Tobacco doisture: Melon

Tobacco Product	New	Original	
Submission tracking	EX0001055	GF1908345	
number			
Product name	Al Fakher Cocktail Flavour 1000 grams Al Fakher Cocktail Flavour 1 K		
Eligibility status	Not applicable Grandfathered		
Marketing order date	Not applicable Not applicable		
Abbreviated report date	Not applicable	Not applicable	
Package type	Plastic Pouch	Plastic pouch	
Package quantity	1000 grams	1000 grams <sup>1</sup>	
Characterizing flavor	Cocktail	Cocktail	
Additional property:	Tobacco Cut Size:	Tobacco Cut Size: 🖁 mm	
	Tobacco Moisture: 🖁 %	Tobacco Moisture: 🔐 %	
Product modifications	Increasing/Decreasing the quantity of Increasing the quantity of	complex purchased flavor <sup>(b) (4)</sup>	
Tobacco Product	flavor <sup>ere</sup>	Original	
Submission tracking	EX0001056	GF1908325	
number			
Product name	Al Fakher Mango Flavour 1000 grams	Al Fakher Mango Flavour 1Kg	
Eligibility status	Not applicable	Grandfathered	
Marketing order date	Not applicable	Not applicable	
Abbreviated report date	Not applicable	Not applicable	
Packagetype	Plastic Pouch	Plastic pouch	
Package quantity	1000 grams	1000 grams <sup>1</sup>	
Characterizing flavor	Mango	Mango	
Additional property:	Tobacco Cut Size: 🔐 mm	Tobacco Cut Size:	
	Tobacco Moisture: 6%	Tobacco Moisture: 🔐 %	
Product modifications	Addition/Deletion of tobacco additives • Deletion of (0)(4) in the com Increasing/Decreasing the quantity of • Increasing the quantity of (0)(4) flavor (0)(4)	nplex purchased flavor <sup>(b)(4)</sup>	

Tobacco Product	New Original	
Submission tracking	EX0001057	GF1908342
number		
Product name	Al Fakher Cocktail Flavour 250 grams	Al Fakher Cocktail Flavour 250 grams
Eligibility status	Not applicable Grandfathered	
Marketing order date	Not applicable Not applicable	
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic pouch
Package quantity	250 grams	250 grams
Characterizing flavor	Cocktail	Cocktail
Additional property:	Tobacco Cut Size:	Tobacco Cut Size: 🖁 mm
	Tobacco Moisture: 🖁 %	Tobacco Moisture: 🔐 %
	Addition/Deletion of tobacco additives	5:
	• Deletion of (b) (4) in the	e complex purchased flavor <sup>(b) (4)</sup>
Product modifications		
	Increasing/Decreasing the quantity of	existing tobacco additives:
	<ul> <li>Increasing the quantity of <sup>(3) (4)</sup></li> </ul>	in the complex purchased
	flavor <sup>(0) (4)</sup>	
Tobacco Product	New	Original
Submission tracking	EX0001058	GF1908301
number		
	Al Fakher Two Apples Flavour 250	Al Fakher Two Apple Flavour 250
number	grams	Al Fakher Two Apple Flavour 250 grams
number Product name Eligibility status		
number Product name	grams	grams
number Product name Eligibility status	grams Not applicable	grams Grandfathered
number Product name Eligibility status Marketing order date	grams Not applicable Not applicable	grams Grandfathered Not applicable
number Product name Eligibility status Marketing order date Abbreviated report date	grams Not applicable Not applicable Not applicable	grams Grandfathered Not applicable Not applicable
number Product name Eligibility status Marketing order date Abbreviated report date Package type	grams Not applicable Not applicable Not applicable Plastic Pouch	grams Grandfathered Not applicable Not applicable Plastic pouch
number Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity	grams Not applicable Not applicable Not applicable Plastic Pouch 250 grams	grams Grandfathered Not applicable Not applicable Plastic pouch 250 grams
number Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor	grams Not applicable Not applicable Plastic Pouch 250 grams Two Apples	grams Grandfathered Not applicable Plastic pouch 250 grams Two Apples
number Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor	grams Not applicable Not applicable Plastic Pouch 250 grams Two Apples Tobacco Cut Size: 11 mm	grams Grandfathered Not applicable Plastic pouch 250 grams Two Apples Tobacco Cut Size: 11 mm Tobacco Moisture: 10%
number Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor	grams Not applicable Not applicable Plastic Pouch 250 grams Two Apples Tobacco Cut Size: 11 mm Tobacco Moisture: 10% Addition/Deletion of tobacco additives	grams Grandfathered Not applicable Plastic pouch 250 grams Two Apples Tobacco Cut Size: 11 mm Tobacco Moisture: 10%
number Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor	grams Not applicable Not applicable Plastic Pouch 250 grams Two Apples Tobacco Cut Size: 11 mm Tobacco Moisture: 10% Addition/Deletion of tobacco additives	grams Grandfathered Not applicable Plastic pouch 250 grams Two Apples Tobacco Cut Size: 11 mm Tobacco Moisture: 10%
number Product name Eligibility status Marketing order date Abbreviated report date Package type Package quantity Characterizing flavor Additional property:	grams Not applicable Not applicable Plastic Pouch 250 grams Two Apples Tobacco Cut Size: 11 mm Tobacco Moisture: 10% Addition/Deletion of tobacco additives • Deletion of Different in the second	grams Grandfathered Not applicable Plastic pouch 250 grams Two Apples Tobacco Cut Size: 11 mm Tobacco Moisture: 10%

Tobacco Product	New	Original	
Submission tracking	EX0001059	GF1908305	
number			
Product name	Al Fakher Two Apples Flavour 1000	Al Fakher Two Apple Flavour 1Kg	
	grams		
Eligibility status	Not applicable	Grandfathered	
Marketing order date	Not applicable	Not applicable	
Abbreviated report date	Not applicable	Not applicable	
Package type	Plastic Pouch	Plastic pouch	
Package quantity	1000 grams	1000 grams <sup>1</sup>	
Characterizing flavor	Two Apples	Two Apples	
Additional property:	Tobacco Cut Size:	Tobacco Cut Size:	
	Tobacco Moisture: 🔐 %	Tobacco Moisture: 🔐 %	
	Addition/Deletion of tobacco additive	es:	
	<ul> <li>Deletion of <sup>(b) (4)</sup> in the</li> </ul>	e complex purchased flavor <sup>(b) (4)</sup>	
Product modifications			
	Addition of <sup>(b) (4)</sup> in t	the complex purchased flavor <sup>(b) (4)</sup>	
Tobacco Product	New	Original	
Submission tracking	EX0001060	GF1908302	
number			
Product name	Al Fakher Two Apples Flavour 50	Al Fakher Two Apples Flavour 50	
	grams	grams	
Eligibility status	Not applicable	Grandfathered	
Marketing order date	Not applicable	Not applicable	
Abbreviated report date	Not applicable	Not applicable	
Packagetype	Plastic Pouch	Plastic pouch	
Package quantity	50 grams	50 grams	
Characterizing flavor	Two Apples	Two Apples	
Additional property:	Tobacco Cut Size: 🙆 mm	Tobacco Cut Size: 🙆 mm	
	Tobacco Moisture: 🔐 %	Tobacco Moisture: 🖁 %	
	Addition/Deletion of tobacco additive	es:	
	Deletion of Did     in the	e complex purchased flavor <sup>(b) (4)</sup>	
Product modifications			
	Addition of (b) (4) in t	the complex purchased flavor <sup>(b) (4)</sup>	
Recommendation			

Technical Project Lead	i (TPL):	Digitally signed by Jeannie H. Jeong-im -S Date: 2020.06.23 14:08:51 -04'00' Jeannie Jeong-Im, Ph.D. Chemistry Branch Chief Division of Product Science
Signatory Decision:		Concur with TPL recommendation and basis of recommendation Concur with TPL recommendation with additional comments (see separate memo)
		Do not concur with TPL recommendation (see separate memo) Digitally signed by Matthew R. Holman -S Date: 2020.06.23 14:20:59 -04'00' Matthew R. Holman, Ph.D. Director

Office of Science

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#### 1. BACKGROUND

# **1.1. ORIGINAL TOBACCO PRODUCTS**

The original tobacco products are waterpipe tobacco filler manufactured by the applicant as indicated on the cover page of this review.

#### **1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW**

On April 14, 2020, FDA received fifteen Exemption Requests (EX0001037, EX0001040, EX0001041, EX0001045, EX0001048 – EX0001050, and EX0001053 – EX0001060) from Troutman Sanders LLP, on behalf of AI Fakher Distribution USA, Inc. On April 29, 2020, FDA received amendment (EX0001068) with the updated certification statements as requested by FDA in a teleconference dated April 28, 2020. On May 5, 2020, FDA received an amendment (EX0001075) in response to OCE's request for information to complete 905(j)(3) status review for all EX Requests. On May 8, 2020, FDA issued an Acceptance letter. On May 12, 2020, FDA received an amendment (EX0001111) in response to OCE's request for additional information to complete 905(j)(3) status review for EX0001045. On May 13, 2020 FDA received an amendment (EX0001114) in response to a follow up request by OCE for additional information.

#### **1.3. SCOPE OF REVIEW**

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

# **1.4. TOBACCO ADDITIVE MODIFICATION**

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

٠	deleting an additive ( <sup>b) (4)</sup> in the complex purchased flavor <sup>b) (4)</sup> in EX0001037, EX0001040, EX0001041
٠	adding an additive <sup>(b) (4)</sup> in the complex purchased flavor <sup>(b) (4)</sup> in EX0001037, EX0001040, EX0001041
٠	deleting an additive ( <sup>b) (4)</sup> in the complex purchased flavor <sup>(b) (4)</sup> in EX0001045 and EX0001056
•	increasing the quantity of an existing additive <sup>(6) (4)</sup> in the complex purchased
	flavor (b) (4) in EX0001045 and EX0001056
•	deleting an additive $(b)(4)$ in the complex purchased flavor $(b)^{(4)}$
	in EX0001048 – EX0001050
•	adding an additive (b) (4) in the complex purchased flavor
	in EX0001048 – EX0001050
•	decreasing the quantity of an existing additive (b) (4) in the complex
	purchased flavor <sup>(0)(4)</sup> in EX0001053 and EX0001054
•	increasing the quantity of an existing additive
	flavor (b) (4) in EX0001053 and EX0001054
٠	deleting an additive(b) (4) in the complex purchased flavor " <sup>b) (4)</sup> in EX0001055 and EX0001057

- increasing the quantity of an existing additive flavor (<sup>(0)(4)</sup>) in the complex purchased in EX0001055 and EX0001057
- deleting an additive (<sup>b) (4)</sup> in the complex purchased flavor <sup>b) (4)</sup>
   in EX0001058 EX0001060
   adding an additive (<sup>b) (4)</sup> in the complex purchased flavor <sup>(b) (4)</sup>
- adding an additive <sup>(0)</sup> (4) in the complex purchased flavor <sup>(0)</sup> (4) in EX0001058 EX0001060

#### 2. REGULATORY REVIEW

Regulatory reviews were completed by Kathryn Mueller on May 8, 2020. The reviews conclude that the Exemption Requests are administratively complete.

# 3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the original tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated May 20, 2020, for EX0001037; May 22, 2020, for EX0001040, EX0001041, EX0001045, EX0001059, and EX0001060; May 23, 2020, for EX0001048- EX0001050, and EX0001053-EX0001057; and May 26, 2020, for EX0001058, conclude that the original tobacco products are grandfathered products. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.<sup>2</sup>

#### 4. SCIENTIFIC REVIEW

A chemistry review was completed by Jikun Liu on June XX, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives, for all EX Requests and increasing and decreasing<sup>3</sup> the quantity of existing tobacco additives in EX0001037, EX0001040, EX0001041, EX0001045, EX0001048 - EX0001050, and EX0001053 – EX0001060. Complex purchased flavors are used in the manufacturing of the original tobacco products, and are additives because their intended use may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of the tobacco products. The review concludes that the modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&CAct). For EX0001037, EX0001040, and EX0001041, tobacco additives were deleted and added in the complex purchased flavor The applicant proposes to delete at the same quantity. and add the extracted from , is widely used to flavor food. This complex purchased flavor is comprised of approximately 83% of and and appear to be interchangeable flavor ingredients. For EX0001058 - EX0001060, the applicant proposes to modify the orginal tobacco products by deleting from the complex flavor in the original tobacco and adding an equal quantity of

<sup>&</sup>lt;sup>2</sup> Any tobacco product that can be sold under the FD&C Act (e.g., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

<sup>&</sup>lt;sup>3</sup> EX0001053 and EX0001054 only

new tobacco products of EX0001037, EX0001040, EX0001041, and EX0001058 – EX0001060 compared to the original tobacco products, and deletion of other $[0,0]$ ingredients such as [0,0] in and $[0,0]$ from the new tobacco products. For EX0001045 and EX0001056, the proposed modification is the deletion of $[0,0]$ from a complex purchased flavor, $[0,0]$ and increasing $[0,0]$ in the new formula. $[0,0]$ is a natural flavor compound present in $[0,0]$ other $[0,0]$ in the new formula. $[0,0]$ occurs in $[b]$ (4) and $[0,0]$ and $[0,0]$ from the complex purchased flavor $[0,0]$ helps to generate odor of some $[0,0]$ varieties. In EX0001048 – EX0001050, the applicant proposes substitution of $(b)(4)$ from the complex purchased flavor $[0,0]$ is one of the main volatile carbonyl species in the vapors of $[0,0]$ . For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of $[0,0]$ in the complex purchased flavor $[0,0]$ is only 0.11% or $[0,0]$ of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete $(b)$ (4) with an equal quantity of $[0,0]$ is only 0.11% or $[0,0]$ with an equal quantity of $[0,0]$ with an equal quantity of $[0,0]$ is only 0.11% or $[0,0]$ with an equal quantity of $[0,0]$ is only 0.11% or $[0,0]$ with an equal quantity of $[0,0]$ is only 0.11% or $[0,0]$ with an equal quantity of $[0,0]$ is only 0.11% or $[0,0]$ with an equal quantity of $[0,0]$ in all of the above EX Requests, the changes in these additives resulted in small changes in total quantity of additives in the complex flavor in the new products is verified in small changes in total quantity of additives in the complex flavor in the sea decreated to the two total equantity of additives in the complex flavor in the complex flavor additive from the complex flavor in the complex flavor additives in total quantity of additives in the complex flavor in the complex flavor additive from the complex flavor additives in total quantity of additives in t	products. These proposed product modifications result in a 20% increase in trans-anethole in the
(b)(4) from the new tobacco products. For EX0001045 and EX0001056, the proposed modification is the deletion of $(0)^{(4)}$ from a complex purchased flavor, $(0)^{(4)}$ and increasing $(0)^{(4)}$ , $(0)^{(4)}$	new tobacco products of EX0001037, EX0001040, EX0001041, and EX0001058 – EX0001060
EX0001056, the proposed modification is the deletion of $0^{14}$ from a complex purchased flavor, $0^{14}$ and increasing $0^{14}$ in the new formula. $0^{14}$ is a natural flavor compound present in $0^{12}$ , other $0^{14}$ , and $0^{14}$ is $0^{14}$ occurs in $(b)^{14}$ helps to generate odor of some $0^{16}$ varieties. In EX0001048 – EX0001050, the applicant proposes substitution of $(b)(4)$ from the complex purchased flavor $0^{14}$ with an equal quantity of $(b)(4)$ in the new tobacco products. $(b)^{14}$ is one of the main volatile carbonyl species in the vapors of $0^{14}$ . For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of $0^{14}$ in the complex purchased flavor $0^{14}$ and increase of $1000\%$ . However, the concentration of this complex flavor in the new products is $0^{14}$ g/g. Therefore, the increase in $0^{14}$ is only 0.11% or $0^{16}$ mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete $(b)^{14}$ with an equal quantity of $0^{14}$ is only 0.11% or $0^{16}$ mg/g of the complex flavor additive $0^{14}$ is only 0.11% or $0^{16}$ mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete $(b)^{14}$ with an equal quantity of $0^{14}$ by increasing the quantity of $0^{14}$ by 0.25% in the complex flavor additive $0^{14}$ by increasing the quantity of additives in	compared to the original tobacco products, and deletion of other <sup>(0)(9)</sup> ingredients such as
flavor, $b^{(4)}$ and increasing $b^{(4)}$ , other $b^{(4)}$ , and $b^{(4)}$ (b)(4) in the new formula. $b^{(4)}$ is a natural flavor compound present in $b^{(4)}$ , other $b^{(4)}$ , and $b^{(4)}$ (b)(4) occurs in (b) (4) occurs in the new tobacco products. (b) (4) occurs is one of the main volatile carbonyl species in the vapors of $b^{(4)}$ . For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of $b^{(4)}$ in the complex purchased flavor $b^{(4)}$ and increasing the level of $b^{(4)}$ is only only the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is $b^{(4)}$ g/g. Therefore, the increase in $b^{(4)}$ is only 0.11% or $b^{(4)}$ with an equal quantity of $b^{(4)}$ with an equal quantity of $b^{(4)}$ is only 0.11% or $b^{(4)}$ with an equal quantity of $b^{(4)}$ with an equal quantity of $b^{(4)}$ is only 0.11% or $b^{(4)}$ with an equal quantity of $b^{(4)}$ with an equal quantity of $b^{(4)}$ is only 0.11% or $b^{(4)}$ with an equal quantity of $b^{(4)}$ is only 0.25% in the complex flavor additive $b^{(4)}$ in total quantity of additives in the set of the difference is additives in total quantity of additives in the properties occurs in t	(0) (d) from the new tobacco products. For EX0001045 and
natural flavor compound present in <sup>(b)(4)</sup> , other <sup>(b)(4)</sup> , and <sup>(b)(4)</sup> , <sup></sup>	EX0001056, the proposed modification is the deletion of from a complex purchased
and has a bland odor, but when combined with other fragrant [1(4)] helps to generate odor of some [10(4)] with an equal quantity of (b)(4) from the complex purchased flavor [10(4)] with an equal quantity of (b)(4) in the new tobacco products. (b) (4) is one of the main volatile carbonyl species in the vapors of [10(4)] and its characteristic odor is similar to (b) (4) . For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of [10(4)] in the complex purchased flavor [10(4)] by the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is [10(4)] g/g. Therefore, the increase in [10(4)] 0.11% or [10(4)] mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete (b) (4) with an equal quantity of [10(4)] by 0.25% in the complex flavor additive [10(4)] EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	flavor, <sup>(b) (4)</sup> in the new formula. <sup>(b) (4)</sup> is a
helps to generate odor of some $[01(4)]$ varieties. In EX0001048 – EX0001050, the applicant proposes substitution of (b)(4) from the complex purchased flavor $[01(4)]$ is one of the main volatile carbonyl species in the vapors of $[01(4)]$ . For EX0001053 – EX0001054, the and its characteristic odor is similar to (b) (4) . For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of $[01(4)]$ in the complex purchased flavor $[01(4)]$ and increasing the level of $[01(4)]$ by the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is $[01(4)]$ g/g. Therefore, the increase in $[01(4)]$ is only 0.11% or $[01(4)]$ with an equal quantity of $[01(4)]$ by increasing the quantity of $[01(4)]$ with an equal quantity of $[01(4)]$ by increasing the quantity of $[01(4)]$ by 0.25% in the complex flavor additive $[01(4)]$ by increasing the quantity of additives in	natural flavor compound present in $(b)$ (4) , other $(b)$ (4) , and $(b)$ (4) occurs in $(b)$ (4) occurs in $(b)$ (4)
proposes substitution of (b)(4) from the complex purchased flavor (b)(4) is one of the main volatile carbonyl species in the vapors of (b)(4) is one of and its characteristic odor is similar to (b) (4) . For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of (b)(4) by the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is (b) (4) with an equal quantity of (b)(4) is only 0.11% or (b)(4) with an equal quantity of (b)(4) with an equal quantity of (b)(4) is only 0.25% in the complex flavor additive (b)(4) is only 0.25% in these additives resulted in small changes in total quantity of additives in	and <sup>(6) (4)</sup> and has a bland odor, but when combined with other fragrant <sup>(6) (4)</sup>
with an equal quantity of $(b)(4)$ in the new tobacco products. $(b)(4)$ is one of the main volatile carbonyl species in the vapors of $b(4)$ . For EX0001053 – EX0001054, the and its characteristic odor is similar to $(b)(4)$ . For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of $b(4)$ in the complex purchased flavor $b(4)$ and increasing the level of $b(4)$ by the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is $b(4)$ g/g. Therefore, the increase in $b(4)$ is only 0.11% or $b(4)$ with an equal quantity of $b(4)$ by increasing the quantity of $b(4)$ with an equal quantity of $b(4)$ by increasing the quantity of $b(4)$ with an equal quantity of $b(4)$ is only location of the above EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	helps to generate odor of some ()(4) varieties. In EX0001048 – EX0001050, the applicant
the main volatile carbonyl species in the vapors of <sup>(0)(4)</sup> . For EX0001053 – EX0001054, the and its characteristic odor is similar to (b) (4). For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of in the complex purchased flavor <sup>(0)(4)</sup> and increasing the level of <sup>(0)(4)</sup> by the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is <sup>(0)(4)</sup> g/g. Therefore, the increase in <sup>(0)(4)</sup> is only 0.11% or <sup>(0)(4)</sup> mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete (b) (4) with an equal quantity of <sup>(0)(4)</sup> by increasing the quantity of <sup>(0)(4)</sup> by 0.25% in the complex flavor additive <sup>(0)(4)</sup> In all of the above EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	proposes substitution of $(b)(4)$ from the complex purchased flavor (b)(4)
and its characteristic odor is similar to (b) (4) . For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of (b)(4) in the complex purchased flavor (b)(4) and increasing the level of (b)(4) by the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is (b)(4) g/g. Therefore, the increase in (b)(4) is only $0.11\%$ or (b)(4) with an equal quantity of (b)(4) with an equal quantity of (b)(4) by increasing the quantity of (b)(4) with an equal quantity of (b)(4) by increasing the quantity of (b)(4) and increase in (c)(4) and increase in (c)(4) and increase in (c)(4) and increase in (c)(4) and (c) (c)(4) and (c	with an equal quantity of (b)(4) in the new tobacco products. (b) (4) is one of
applicant proposes to modify the original tobacco products by decreasing the quantity of <sup>(b)(4)</sup> in the complex purchased flavor <sup>(b)(4)</sup> and increasing the level of <sup>(b)(4)</sup> by the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is <sup>(b)(4)</sup> g/g. Therefore, the increase in <sup>(b)(4)</sup> is only 0.11% or <sup>(b)(4)</sup> mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete (b) (4) with an equal quantity of <sup>(b)(4)</sup> by increasing the quantity of <sup>(b)(4)</sup> by 0.25% in the complex flavor additive <sup>(b)(4)</sup> In all of the above EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	the main volatile carbonyl species in the vapors of <sup>(0)(4)</sup>
in the complex purchased flavor $[01(4)]$ and increasing the level of $[01(4)]$ by the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is $[01(4)]$ g/g. Therefore, the increase in $[01(4)]$ is only 0.11% or $[01(4)]$ mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete (b) (4) with an equal quantity of $[01(4)]$ by increasing the quantity of $[01(4)]$ by 0.25% in the complex flavor additive $[01(4)]$ for $[01(4)]$ and $[01(4)]$ in all of the above EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	and its characteristic odor is similar to (b) (4) For EX0001053 – EX0001054, the
by the same quanity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is $[0,(4)]$ g/g. Therefore, the increase in $[0,(4)]$ is only 0.11% or $[0,(4)]$ mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete (b) (4) with an equal quantity of $[0,(4)]$ by increasing the quantity of $[0,(4)]$ by 0.25% in the complex flavor additive $[0,(4)]$ In all of the above EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	applicant proposes to modify the original tobacco products by decreasing the quantity of
complex flavor in the new products is (9)(4) g/g. Therefore, the increase in (9)(4) is only 0.11% or (9)(4) mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete (b) (4) with an equal quantity of (9)(4) by increasing the quantity of (9)(4) by 0.25% in the complex flavor additive (9)(4) In all of the above EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	in the complex purchased flavor <sup>(010)</sup> and increasing the level of <sup>(0)(4)</sup>
0.11% or <sup>(b) (4)</sup> mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete (b) (4) with an equal quantity of <sup>(b) (4)</sup> by increasing the quantity of <sup>(b) (4)</sup> by 0.25% in the complex flavor additive <sup>(b) (4)</sup> In all of the above EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	by the same quanity, which is an increase of 1000%. However, the concentration of this
proposes to delete (b) (4) with an equal quantity of <sup>(b) (4)</sup> by increasing the quantity of <sup>(b) (4)</sup> by 0.25% in the complex flavor additive <sup>(b) (4)</sup> In all of the above EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	complex flavor in the new products is (0)(4) g/g. Therefore, the increase in (0)(4) is only
of bitter by 0.25% in the complex flavor additive bitter by 0.25\% in the	0.11% or <sup>b)(9)</sup> mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant
EX Requests, the changes in these additives resulted in small changes in total quantity of additives in	proposes to delete (b) (4) with an equal quantity of by increasing the quantity
	of <sup>(0)(4)</sup> by 0.25% in the complex flavor additive <sup>(0)(4)</sup> In all of the above
alle server the base of the server of the server stand the set of the server base of the base of the server base of the server of t	EX Requests, the changes in these additives resulted in small changes in total quantity of additives in
the new tobacco products and are not expected to affect or after smoke yields between the new	the new tobacco products and are not expected to affector alter smoke yields between the new
and original tobacco products. Additionally, the modifications are not expected to materially affect	and original tobacco products. Additionally, the modifications are not expected to materially affect
any other characteristic (materials, ingredients, design, composition, heating source, or other	any other characteristic (materials, ingredients, design, composition, heating source, or other
features) of the tobacco products.	features) of the tobacco products.

# 5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on June 4, 2020.

The final environmental review found that the applicant did not provide: the marketing intention for the original products after receiving the marketing orders for the new products; a statement if the new products are intended to replace or substitute the other waterpipe tobacco products currently in the market; and a full environmental assessment with marketing of the proposed products on disproportionately high and adverse human health or environmental effects on low-income, minority or native/indigenous populations. Therefore, additional information is needed to determine whether to prepare an environmental impact statement (EIS) or finding of no significant impact (FONSI).

# 6. CONCLUSION AND RECOMMENDATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

deleting an additive (a) (4) in the complex purchased flavor (b) (4) in EX0001037, EX0001040, EX0001041

<ul> <li>adding an additive <sup>(0)(4)</sup>/<sub>(1)</sub> in the complex purchased flavor <sup>(0)(4)</sup></li> <li>in EX0001037, EX0001040, EX0001041</li> </ul>
• deleting an additive ( <sup>0)(4)</sup> in the complex purchased flavor <sup>(0)(4)</sup> in EX0001045 and EX0001056
<ul> <li>increasing the quantity of an existing additive field for the complex purchased flavor flavor</li></ul>
<ul> <li>deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001048 – EX0001050</li> </ul>
• adding an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001048 – EX0001050
<ul> <li>decreasing the quantity of an existing additive <sup>(b)(4)</sup> in the complex purchased flavor <sup>(b)(4)</sup> in EX0001053 and EX0001054</li> </ul>
• increasing the quantity of an existing additive <sup>(b) (4)</sup> in the complex purchased flavor <sup>(b) (4)</sup> in EX0001053 and EX0001054
<ul> <li>deleting an additive ((b) (4) in the complex purchased flavor (b) (4) in EX0001055 and EX0001057</li> </ul>
<ul> <li>increasing the quantity of an existing additive filled in the complex purchased flavor flavor</li></ul>
<ul> <li>deleting an additive <sup>(b)(4)</sup></li> <li>in the complex purchased flavor <sup>(b)(4)</sup></li> <li>in EX0001058 – EX0001060</li> </ul>
<ul> <li>adding an additive <sup>(b)(4)</sup></li> <li>in the complex purchased flavor <sup>(b)(4)</sup></li> <li>in EX0001058 – EX0001060</li> </ul>

I concur with the conclusion of the scientific review that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines 'additive' as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), ... "I concur with the scientific review that the changes in <sup>(D)(4)</sup>

complex flavors represent adding or deleting tobacco additives for all EX Requests and increasing or decreasing the quantity of existing tobacco additives. In addition, it is my conclusion that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new tobacco products to be marketed would be appropriate for the protection of the public health. The and addion of <sup>(D)(4)</sup>mg/g of modifications are as follows: deletion of mg/g of for EX0001037, EX0001040 and in the complex purchased flavor and increasing in the EX0001041; deletion of /g of mg/g of for EX0001045 and EX0001056; deletion of complex flavor additive mg/g of (b) (4) and addtion of mg/got(b)(4)in the complex purchased flavor for EX0001048-EX0001050; decreasing mg/g of and increasing mg/g of in the complex purchased flavor for EX0001053 – EX0001054; deletion of mg/g of (b) (4) andincreasing mg/g of in the complex flavor additive and deletion of mg/g of and addition of 🙆 mg/g of in the complex purchased flavor

for EX0001058 – EX0001060. In all of the above EX Requests, the change in these additives resulted in small changes in total quantity of additives in the new tobacco products and are not expected to affect or alter smoke yields between the new and original tobacco products. Additionally, the modifications are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP's scientific understanding, that an exemption for these modifications are otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

FDA has examined the environmental effects of finding these new tobacco products exempt from substantial equivalence and found that additional information is necessary to determine the impact of the action. Without this information, FDA may be precluded or delayed from issuing an EX order.

An Environmental Information Request letter should be issued requesting the following information:

1. All of your EX Requests lack information regarding marketing of the original tobacco products after receiving marketing orders for the new tobacco products. Marketing information is used to assess the cumulative environmental impacts of concurrent manufacturing, use, and disposal of the new and original tobacco products. You stated that the original products are currently not marketed to consumers in the United States. Clarify whether the new and corresponding original tobacco products would be marketed simultaneously after receiving marketing orders for the new tobacco products, or if the original tobacco products will continue to not be marketed to consumers in the United States. If the original tobacco products will be marketed, provide the projected market volumes in the first and fifth years of marketing the new tobacco products. Table 1 may be used to provide this information, or you can submit this information using an alternative approach if it provides the first- and fifth-year market volume projections for the original tobacco products.

Original Tobacco Product	Unit	First Year	Fifth Year
Al Fakher Apple Flavour 1 Kg	ļ.		
(GF1908361)			
Al Fakher Apple Flavour 50 grams			
(GF1908359)			
Al Fakher Apple Flavour 250 grams			
(GF1908360)			
Al Fakher Mango Flavour 250 grams			
(GF1908321)			

Table 1. Market volume projections for the original tobacco products

Al Fakher Strawberry Flavour 1 Kg (GF1908306)		
Al Fakher Strawberry Flavour 50 grams (GF1908308)		
Al Fakher Strawberry Flavour 250 grams (GF1908303)		
Al Fakher Melon Flavour 250 grams (GF1908324)		
Al Fakher Melon Flavour 1 Kg (GF1908323)		
Al Fakher Cocktail Flavour 1 Kg (GF1908345)		
Al Fakher Mango Flavour 1 Kg (GF1908325)		
Al Fakher Cocktail Flavour 250 grams (GF1908342)		
Al Fakher Two Apples Flavour 250 grams (GF1908301)		
Al Fakher Two Apples Flavour 1 Kg (GF1908305)		
Al Fakher Two Apples Flavour 50 grams (GF1908302)		

- 2. All of your EX Requests lack information regarding if the new tobacco products are intended to compete with or replace portions of other waterpipe tobacco products currently on the market. Provide a statement if the new tobacco products are intended to compete with or replace portions of other waterpipe tobacco products currently on the market. The information about marketing of the new tobacco products are used to assess the environmental impacts of the proposed actions.
- 3. All of your EX Requests provided an environmental assessment, however the environmental assessment does not address whether marketing of the proposed product is likely to have a disproportionately high and adverse human health or environmental effects on low- income, minority or native/indigenous populations. Provide an evaluation addressing the impacts of marketing of your proposed products regarding environmental justice and if applicable any proposed mitigation strategies. This information will support our assessment of environmental justice as it relates to impacts on low-income, minority, or native/indigenous populations. For more information on environmental justice please refer to: <a href="https://www.epa.gov/environmentaljustice/environmental-justice-and-national-environmental-policy-act">https://www.epa.gov/environmentaljustice/environmentaljustice/environmental-justice-and-national-environmental-policy-act</a>.

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order should be issued for the new tobacco products in EX0001037, EX0001040, EX0001041, EX0001045, EX0001048 – EX0001050, and EX0001053 – EX0001060, as identified on the cover page of this review.